

REMARKS

Claims 1-19 were pending in this application. Claim 8 has been amended. No new matter has been added.

ARGUMENTS

Claim 8 is rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 has been amended to recite the specific elements referred to as rare earth elements.

Claims 1-3, 5-7, 9, 16 and 18 are rejected under 35 USC 103(a) as being unpatentable over Heublein et al. (U.S. Patent Publication No. 2002/0004060), in view of Stinson et al. (U.S. Patent No. 6,340,367).

Claims 11 and 13-14 are rejected under 35 USC 103(a) as being unpatentable over Heublein et al. in view of Stinson et al.

Claims 12 and 15 are rejected under 35 USC 103(a) as being unpatentable over Heublein et al., in view of Stinson et al.

Claims 4, 10 and 19 are rejected under 35 USC 103(a) as being unpatentable over Heublein et al., in view of Stinson et al., as applied to Claim 1 above, and in further view of Chandrasekaran et al. (U.S. Patent Publication No. 2003/0153971).

Claims 8 and 17 are rejected under 35 USC 103(a) as being unpatentable over Heublein et al., in view of Stinson et al., as applied to Claim 1 above, and in further view of Meyer-Lindenberg et al. (U.S. Patent Publication No. 2004/0241036).

Heublein relates only to stent construction and does not disclose, teach or suggest using a radiopaque marker.

Stinson relates to radiopaque markers for implantable stents. However, Stinson relates to structures which are separate from the stent itself and which attach to, form around or are otherwise temporarily and removably associated with the stent. An object of Stinson is to provide a marker 14 that can be removed from the stent. Stinson teaches away from permanent radiopaque markers. See, col. 2, lines 24-49, discussing the disadvantages of permanent markers and the advantages of “temporary retrievable markers” on an implantable endoprosthesis. Stinson does not disclose, teach or suggest biodegradable stents or the use of a radiopaque marker that forms a part of the stent. Accordingly, there is no motivation in Stinson to adapt the radiopaque marker to be used as a non-temporary integral part (e.g., coating) of the stent material itself. Stinson does not anticipate the experimentation and ingenuity necessary to produce a radiopaque stent that possesses desirable biodegradability. There is no reason in Stinson to modify Stinson’s marker as it is a separate structure. Stinson does not need to take biodegradability into account in the Stinson marker structure as it is removed prior to degradation appreciably occurring. In contrast, the radiopaque marker of the present application forms a part of stent prior to implantation and essentially remains part of the stent. The marker of the present application must be designed to take into account desirable marker opacity properties, while enabling the stent material to retain the desired degradability properties. One with ordinary skill in the art would not be motivated to modify a temporary separate opaque marker structure to form a marker material as presented in the present application for use with a biodegradable stent. In short, Stinson addresses a completely different problem (i.e., providing a retrievable temporary stent marker structure) than that addressed in the instant application (e.g., providing a biodegradable stent with radiopacity). The materials selected by Stinson do not necessarily lead one with ordinary skill in the art to the materials of the present disclosure as claimed.

Furthermore, the materials (atomic elements) listed in Stinson differ from those in the present application. Stinson cites an atomic element range of about 22 to about 83 (see col. 4, line 8), yet provides no experimental results. This is not an enabling disclosure of the entire atomic element range; rather, it is an invitation to experiment. Undue experimentation is required to determine which atomic elements would be usable to provide the requisite opacity properties, what percentages of the materials would be usable and what thickness of the layering would work. Moreover, it is not at all evident from Stinson whether all the atomic elements within the

range would provide a marker which would result in the stent having the desired biodegradability properties. For example, one element within the range Stinson discloses might provide requisite opacity, yet a coating with such material might be too thick and not allow the stent material to degrade at a rate that is practicable.

Additionally, the amounts of the elements used in Stinson are not comparable to those in the present application, as the present application uses weight-percent, whereas Stinson uses marker thicknesses and the linear attenuation coefficient.

Meyer-Lindenberg et al. (Meyer) does not disclose, teach or suggest the use of markers. Meyer discloses the use of yttrium in an amount of 0.01-7 wt % as part of the alloy material MGZn₂Y12 for use in promoting corrodibility (see paragraph 0030). Meyer does not disclose, teach or suggest the use of yttrium as a radiopaque substance. Additionally, the present application claims a marker in which the radiopaque element (e.g., yttrium) is present in a range of 10-90 wt %. This range is outside of the range disclosed in Meyer. It would not have been obvious for one skilled in the art, nor has any motivation been shown, to take a lower range of a material disclosed for its corrosion properties when incorporated into the stent itself and adapt its use to be a radiopaque marker element (see paragraph 0021 of the present application) and increase the usable wt. % range. Meyer does not disclose, teach or suggest using a wt. % range higher than 7.

Therefore, the cited combinations of Heublein, Stinson, Meyer do not make out a prima facie case of obviousness of the referenced claims.

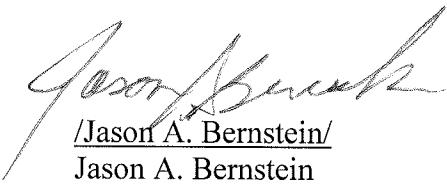
Chandrasekaran et al. is cited as teaching the use of polylactides, chitosan and hyalauronic acid polymers which, in combination with Heublin and Stinson, is stated as rendering Claims 4, 10 and 19 of the present invention obvious. The unique radiopaque marker of the present application has been shown above as being nonobvious over the cited art. The use of these polymers as described in Chandrasekaran does not render the entire invention as claimed obvious as the other aspects of the claimed invention are not obvious.

CONCLUSION

Applicant submits that the patent application is in condition for allowance and respectfully requests such action. If the Examiner has any questions that can be answered by telephone, please contact the undersigned attorney of record at the telephone number listed below.

Respectfully submitted,

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